DOCKET NO:	BOARD MEETING:	PROJECT NO:	PROJECT COST:
H-12	April 17, 2012	11-099	Original: \$3,025,690
	TY NAME: Care Prairie Meadows	CITY: Libertyville	
TYPE OF PROJECT		Ziverty vine	HSA: VIII

PROJECT DESCRIPTION: Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care Prairie Meadows, LLC (the applicants) are proposing the establishment of a 12-station End Stage Renal Dialysis (ESRD) facility located 7,275 GSF of leased space in Libertyville. The cost of the project is \$3,025,690.

The State Board Staff Notes the applicants deferred this project to the April 2012 State Board Meeting.

EXECUTIVE SUMMARY

525 WEST JEFFERSON ST. ● SPRINGFIELD, ILLINOIS 62761 ●(217) 782-3516 FAX: (217) 785-4111

PROJECT DESCRIPTION:

- Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care Prairie Meadows, LLC (the applicants) are proposing the establishment of a 12-station End Stage Renal Dialysis (ESRD) facility located 7,275 GSF of leased space in Libertyville.
- The cost of the project is \$3,025,690.
- The anticipated project completion date is March 31, 2014.

WHY THE PROJECT IS BEFORE THE STATE BOARD:

• To establish a health care facility as defined by Illinois Health Facilities Planning Act.

PURPOSE OF THE PROJECT:

- To establish an ESRD facility and ESRD services to serve the Libertyville/Grayslake area.
- To keep dialysis access available to a growing patient population in HSA-VIII, and the Libertyville/Grayslake areas.

NEED:

- To establish a dialysis service
 - 1. there must be a calculated need in the planning area;
 - 2. the proposed service must provide service to planning area residents;
 - 3. there must be a demand for the service in the planning area;
 - 4. the proposed service must improve access;
 - 5. the proposed service will not cause an unnecessary duplication of service or maldistribution of service; and,
 - 6. will not reduce the utilization of other area providers.
- HSA-VIII currently has an excess of 16 stations.
- Dr. Trob's practice has identified 211 pre-ESRD patients in the immediate Libertyville area, and expects 119 of these patients to need dialysis services within the first two years of the proposed facility's operation.

BACKGROUND/COMPLIANCE ISSUES

Neither applicant has outstanding compliance issues with the State Board.

PUBLIC HEARING/COMMENT

- No public hearing was requested and no letters of opposition were received. Letters of support for this project were received by the State Board Staff. An example of support comments that were received is below:
- Advocate Condell Medical Center stated "it is well known that there is an increasing

need for dialysis service in our nation, in part due to the growing epidemic of diabetes. This epidemic exists in Lake County, where it is complicated by an aging population. Fresenius Medical Care has a long history of providing high quality dialysis care to dialysis patients in Illinois."

FINANCIAL AND ECONOMIC FEASIBILITY

- Internal sources (Cash and Securities/Fair Market Value of the Leases)
- A review of the financial statements indicates sufficient cash is available to fund the project.

CONCLUSIONS:

- There is a calculated excess of 16 stations in the HSA-VIII ESRD service area.
- There are 7 facilities within a 30-minute drive radius.
- Of these 7 facilities, 4 are not at target occupancy. See Table Four below.

State Board Standards Not Met				
Criteria	Reasons for Non-Compliance			
1110.234(a) - Size of Project	Size of project is 606 DGSF per station, which			
	is over the maximum allowable size by 86			
	GSF. (State Standard: 520 GSF/station)			
1110.1430(b) - Planning Area Need	There is an excess of 16 stations in the HSA			
	VIII planning area and existing facilities			
	within 30 minutes are not operating at target			
	occupancy.			
1110.1430(c) - Unnecessary Duplication of	of 4 of the 7 ESRD facilities in the service area are			
Service/Maldistribution	operating beneath the 80th percentile.			

STATE BOARD STAFF REPORT Fresenius Medical Care Prairie Meadows PROJECT #11-099

Applicants	Fresenius Medical Care Holdings, Inc.	
	Fresenius Medical Care Prairie Meadows, LLC	
Facility Name	Fresenius Medical Care Prairie Meadows	
Location	Libertyville	
Application Received	October 21, 2011	
Application Deemed Complete	October 24, 2011	
Review Period Ended	December 23, 2011	
Review Period Extended by the State Board Staff	No	
Public Hearing Requested	No	
Applicants' Deferred Project	No	
Can Applicants Request Another Deferral?	Yes	
Project Completion Date	March 31, 2014	

I. The Proposed Project

The State Board is being asked to consider the establishment of a 12-station ESRD facility in Libertyville. The proposed facility will be located in 7,275 GSF of leased space, and the cost of the project is \$3,025,690. The anticipated project completion date is March 31, 2014.

II. Summary of Findings

- A. The State Board Staff finds the proposed project does **not** appear to be in conformance with the provisions of Part 1110.
- B. The State Board Staff finds the proposed project appears to be in conformance with the provisions of Part 1120.

III. General Information

The proposed facility will be located at 900 Technology Drive, Libertyville. The applicants are Fresenius Medical Care Prairie Meadows, LLC, and Fresenius Medical Care Holdings, Inc. Fresenius Medical Care Holdings, Inc is the parent organization for all the entities and 900 Technology 1.0, LLC, owns the site. Fresenius Medical Care Prairie Meadows, LLC d/b/a Fresenius Medical Care Prairie Meadows is the operating entity/licensee. The proposed facility will be

located in HSA-VIII. HSA-VIII is comprised of Kane, Lake, and McHenry counties in northern Illinois. The March 2012 update to the IDPH Inventory of Health Care Facilities ("Inventory") shows an excess of 16 stations in HSA VIII.

There is no land acquisition cost for this project, as the proposed facility will be leased space with the interior being built out by the applicant. This is a substantive project subject to both a Part 1110 and Part 1120 review. Project obligation will occur after permit issuance. **The anticipated project completion date is March 31, 2014.**

A public hearing was offered on this project; however, no hearing was requested. The State Board Staff received no letters of opposition. Letters of support were received by the State Board Staff. An example of support comments that were received is below:

Advocate Condell Medical Center stated "it is well known that there is an increasing need for dialysis service in our nation, in part due to the growing epidemic of diabetes. This epidemic exists in Lake County, where it is complicated by an aging population. Fresenius Medical Care has a long history of providing high quality dialysis care to dialysis patients in Illinois."

IV. The Proposed Project - Details

The applicants propose to establish a 12 station ESRD facility housed in 7,275 Gross Square Feet ("GSF") of leased space. The proposed facility will be located in Libertyville/Lake County (HSA-VIII), and the applicants note that it will build out the interior of the leased space, and the total estimated project cost is \$3,025,690.

V. <u>Project Costs and Sources of Funds</u>

The total estimated project cost is \$3,025,690. The proposed project is being funded with cash and securities totaling \$1,444,727, and leases with a Fair Market Value of \$1,580,963. Table One outlines the project's costs and uses of funds. The State Board Staff notes all costs are classified as being clinical.

TABLE ONE

Project Uses and Sources of Funds

Uses of Funds	Clinical
Modernization Contracts	\$949,388
Contingencies	\$94,939
A & E Fees	\$104,400
Moveable Equipment	\$296,000
Fair Market Value of Leased Space/Equipment	\$1,580,963
Total Uses of Funds	\$3,025,690
Sources of Funds	Clinical
Cash and Securities	\$1,444,727
Leases (fair market value)	\$1,580,963
Total Sources of Funds	\$3,025,690

VI. <u>Cost/Space Requirements</u>

Table Two displays the project's cost/space requirements for the project. The clinical portion comprises approximately 100% of the cost and GSF.

TABLE TWO							
Fresenius Medical Care Prairie Meadows-Cost/Space Allocation							
Clinical	Existing						
Department	Cost GSF Proposed GSF New Modernized Vacated As Is						
ESRD	\$3,025,690	0	7,275	0	7,275	0	0
Total	Total \$3,025,690 0 7,275 0 7,275 0 0						

VII. <u>Section</u> <u>1110.230 - Project Purpose, Background and Alternatives</u>

A. Criterion 1110.230(a) - Background of Applicant

The Criterion states:

"1) an applicant must demonstrate that it is fit, willing and able, and has the qualifications, background and character, to adequately provide a proper standard of health care service for the community. [20 ILCS 3960/6] In evaluating the qualifications, background and character of the applicant, HFPB shall consider whether adverse action has been taken against the applicant, or against any health care facility owned or operated by the

applicant, directly or indirectly, within three years preceding the filing of the application. A health care facility is considered "owned or operated" by every person or entity that owns, directly or indirectly, an ownership interest. If any person or entity owns any option to acquire stock, the stock shall be considered to be owned by such person or entity (refer to 77 Ill. Adm. Code 1100 and 1130 for definitions of terms such as "adverse action", "ownership interest" and "principal shareholder").

- 2) Examples of facilities owned or operated by an applicant include:
 - A) The applicant, Partnership ABC, owns 60% of the shares of Corporation XYZ, which manages the Good Care Nursing Home under a management agreement. The applicant, Partnership ABC, owns or operates Good Care Nursing Home.
 - B) The applicant, Healthy Hospital, a corporation, is a subsidiary of Universal Health, the parent corporation of Healthcenter Ambulatory Surgical Treatment Center (ASTC), its wholly-owned subsidiary. The applicant, Healthy Hospital, owns and operates Healthcenter ASTC.
 - C) Dr. Wellcare is the applicant. His wife is the director of a corporation that owns a hospital. The applicant, Dr. Wellcare, owns or operates the hospital.
 - D) Drs. Faith, Hope and Charity own 40%, 35% and 10%, respectively, of the shares of Healthfair, Inc., a corporation, that is the applicant. Dr. Charity owns 45% and Drs. Well and Care each own 25% of the shares of XYZ Nursing Home, Inc. The applicant, Healthfair, Inc., owns and operates XYZ Nursing Home, Inc.
- 3) The applicant shall submit the following information:
 - A) A listing of all health care facilities currently owned and/or operated by the applicant, including licensing, certification and accreditation identification numbers, as applicable;
 - B) A certified listing from the applicant of any adverse action taken against any facility owned and/or operated by the applicant during the three years prior to the filing of the application;
 - C) Authorization permitting HFPB and Illinois Department of Public Health (IDPH) access to any documents necessary to verify the information submitted, including, but not limited to: official records of IDPH or other State agencies;

the licensing or certification records of other states, when applicable; and the records of nationally recognized accreditation organizations. Failure to provide the authorization shall constitute an abandonment or withdrawal of the application without any further action by HFPB.

If, during a given calendar year, an applicant submits more than one application for permit, the documentation provided with the prior applications may be utilized to fulfill the information requirements of this criterion. In such instances, the applicant shall attest that the information has been previously provided, cite the project number of the prior application, and certify that no changes have occurred regarding the information that has been previously provided. The applicant is able to submit amendments to previously submitted information, as needed to update and/or clarify data.

The applicant provided a list of all health care facilities currently owned and/or operated by the applicant, including licensing, certification and accreditation identification numbers, a certified statement from the applicant that no adverse action has been taken against any facility owned and/or operated by the applicant during the three years prior to the filing of the application, and authorization permitting HFPB and Illinois Department of Public Health (IDPH) access to any documents necessary to verify the information submitted. The applicants appear fit, willing and able and have the qualifications, background and character to adequately provide a proper standard of healthcare service for the community.

B. Safety Net Impact Statement/Charity Care

The establishment of the Fresenius Medical Care Prairie Meadows dialysis facility will not have any impact on safety net services in the community. Outpatient dialysis services are not typically considered "safety net" services, to the best of our knowledge. However, we do provide care for patients in the community who are economically challenged and/or who are undocumented aliens, who do not qualify for Medicare/Medicaid. We assist patients who do not have insurance in enrolling when possible in Medicaid and/or Medicaid as applicable, and also our social services department assists patients who have issues regarding transportation and/or who are wheel chair bound or have other disabilities which

require assistance with respect to dialysis services and transport to and from the unit.

This particular application will not have an impact on any other safety net provider in the area, as no hospital within the area provides dialysis services on an outpatient basis.

Fresenius Medical Care is a for-profit publicly traded company and is not required to provide charity care, nor does it do so according to the Board's definition. However, Fresenius provides care to all patients regardless of their ability to pay. There are a number of patients treated by Fresenius who either do not qualify for or will not seek any type of coverage for dialysis services. These patients are considered "self-pay" patients. These patients are invoiced as all patients are invoiced, however payment is not expected and Fresenius does not initiate any collections activity on these accounts. These unpaid invoices are written off as bad debt. Fresenius notes that as a for profit entity, it does pay sales, real estate and income taxes. It also does provide community benefit by supporting various medical education activities and associations, such as the Renal Network and National Kidney Foundation.

The applicants do not provide charity care as that term is defined by the State Board. Table Three documents the amount of care provided to Medicaid patients for the three fiscal years prior to submission of the application for all Fresenius Medical Care facilities in Illinois. This includes in-center hemodialysis, peritoneal dialysis, home hemodialysis & sub-acute hemodialysis. State Board Staff notes in the application for permit is a schedule of all Fresenius Dialysis facilities in Illinois their unreimbursed costs, the number of patients who received unreimbursed care, the number of Medicaid patients and the amount of Medicaid revenue. See pages 92-95 of the application for permit.

B. <u>Safety Net Impact Statement/Charity Care</u>

The establishment of the Fresenius Medical Care Du Quoin dialysis facility will not have any impact on safety net services in the community. This is based on the fact that the project consists of the discontinuation and re-establishment of a 10-bed ESRD facility, and the addition of one ESRD station to serve isolation patients. Outpatient dialysis services are not typically considered "safety net" services. However, based on the availability of services in HSA-05, it may be considered a safety net service. This particular application will not have an

impact on any other safety net provider in the area because there appears to be only two other ESRD facilities in a 45-minute drive radius.

Fresenius Medical Care is a for-profit publicly traded company and is not required to provide charity care, nor does it do so according to the Board's definition. However, Fresenius provides care to all patients regardless of their ability to pay. There are a number of patients treated by Fresenius who either do not qualify for or will not seek any type of coverage for dialysis services. These patients are considered "self-pay" patients. These patients are invoiced as all patients are invoiced, however payment is not expected and Fresenius does not initiate any collections activity on these accounts. These unpaid invoices are written off as bad debt. Fresenius notes that as a for profit entity, it does pay sales, real estate and income taxes. It also does provide community benefit by supporting various medical education activities and associations, such as the Renal Network and National Kidney Foundation.

The table below shows the amount of Medicaid care provided for all Fresenius Medical Care facilities in Illinois and the amount of care provided to Medicaid patients for the three fiscal years prior to submission of the application for all Fresenius Medical Care facilities in Illinois. This includes in-center hemodialysis, peritoneal dialysis, home hemodialysis & sub-acute hemodialysis. Fresenius Medical Care Holdings, Inc. provides. State Board Staff notes in the application for permit is a schedule of all Fresenius Dialysis facilities in Illinois their unreimbursed costs, the number of patients who received unreimbursed care, the number of Medicaid patients and the amount of Medicaid revenue. See pages 135-141 of the application for permit

TABLE THREE Safety Net Impact Statement						
CHARITY CARE	CHARITY CARE 2008 2009 2010					
Charity Uncomp patients	282	243	143			
Charity Uncomp treatments	14,557	15,457	7,047			
Charity Uncomp Cost	\$3,402,665	\$3,489,213	\$1,307,433			
MEDICAID						
Medicaid (Patients)	1,561	1,723	1,809			
Medicaid (Revenue)	\$36,159,588	\$39,748,886	\$43,795,183			

C. Criterion 1110.230(b) - Purpose of the Project

The Criterion states:

The applicant shall document that the project will provide health services that improve the health care or well-being of the market area population to be served. The applicant shall define the planning area or market area, or other, per the applicant's definition.

- The applicant shall address the purpose of the project, i.e., identify the issues or problems that the project is proposing to address or solve. Information to be provided shall include, but is not limited to, identification of existing problems or issues that need to be addressed, as applicable and appropriate for the project. Examples of such information include:
 - A) The area's demographics or characteristics (e.g., rapid area growth rate, increased aging population, higher or lower fertility rates) that may affect the need for services in the future;
 - B) The population's morbidity or mortality rates;
 - C) The incidence of various diseases in the area;
 - D) The population's financial ability to access health care (e.g., financial hardship, increased number of charity care patients, changes in the area population's insurance or managed care status);
 - E) The physical accessibility to necessary health care (e.g., new highways, other changes in roadways, changes in bus/train routes or changes in housing developments).
- 2) The applicant shall cite the source of the information (e.g., local health department Illinois Project for Local Assessment of Need (IPLAN) documents, Public Health Futures, local mental health plans, or other health assessment studies from governmental or academic and/or other independent sources).
- The applicant shall detail how the project will address or improve the previously referenced issues, as well as the population's health status and well-being. Further, the applicant shall provide goals with quantified and measurable objectives with specific time frames that relate to achieving the stated goals.
- 4) For projects involving modernization, the applicant shall describe the conditions being upgraded. For facility projects, the applicant shall include statements of age and condition and any

regulatory citations. For equipment being replaced, the applicant shall also include repair and maintenance records.

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The applicants propose to establish a 12-station ESRD facility in 7,275 gross square feet of modernized, leased space. The applicants state that the purpose of the proposed project is to keep dialysis access available to the patient population in HSA-VIII as they continue to monitor the growth of ESRD need and provide responsible healthcare planning as well. The applicants note Dr. Joshua R. Trob, M.D., has seen the number of pre-ESRD patients in his practice double in the past two years, to 215 patients in 2011. In order to meet the future need for ESRD services in the Grayslake/Libertyville area, FMC Prairie Meadows is proposed.

Table Four identifies facilities within a 30-minute time frame and their utilization as supplied by the applicants. The applicants provided a travel time study performed and attested to by Professional Traffic Operations Engineer. The State Board Staff have accepted this study. As seen in the Table, 4 of the 7 facilities within a 30-minute travel radius are below the State Standard (80%), for utilization.

Faci	lities within 30 m	TABLE FOUL		Meadows (1)		
Tach	City	Adjusted Minutes (1)	Stations	December 2011 Utilization	State Board Target Occupancy	Met 80% Standard
DaVita Lake County Dialysis	Libertyville	11.5	16	73.96%	80%	No
FMC Mundelein	Mundelein	13.8	12	2.78%	80%	No
FMC Lake Bluff	Lake Bluff	17.25	16	91.67%	80%	Yes
Neomedica Gurnee	Gurnee	16.1	14	102.38%	80%	Yes
FMC Round Lake	Round Lake	16.1	16	82.29%	80%	Yes
DSI Waukegan	Waukegan	24.15	22	70.45%	80%	No
DaVita Lake Villa Dialysis	Lake Villa	25.3	12	41.67%	80%	No
Average utilization						
 Mileage calculated using *Recently approved facility 			77 IAC 1100	0.510 (d)	l	

The applicants cited quantifiable goals as being the ability to improve access while monitoring patient demand, and that the facility will achieve quality outcomes as demonstrated by achieving 92% of patients having a URR greater than or equal to 65%, and 95% of patients having a Kt/V greater than or equal to 1.2.

D. Criterion 1110.230(c) - Alternatives to the Proposed Project

The Criterion states:

"The applicant shall document that the proposed project is the most effective or least costly alternative for meeting the health care needs of the population to be served by the project.

- 1) Alternative options shall be addressed. Examples of alternative options include:
 - A) Proposing a project of greater or lesser scope and cost;
 - B) Pursuing a joint venture or similar arrangement with one or more providers or entities to meet all or a portion of the project's intended purposes; developing alternative settings to meet all or a portion of the project's intended purposes;
 - C) Utilizing other health care resources that are available to serve all or a portion of the population proposed to be served by the project; and
 - D) Other considerations.
- 2) Documentation shall consist of a comparison of the project to alternative options. The comparison shall address issues of cost, patient access, quality and financial benefits in both the short term (within one to three years after project completion) and long term. This may vary by project or situation.
- 3) The applicant shall provide empirical evidence, including quantified outcome data that verifies improved quality of care, as available."

The applicants propose a 12-station ESRD facility. The applicants considered the following alternatives:

1. Utilize Other Health Care Resources

The applicants note the option of sending pre-ESRD patients to underutilized facilities in the area is not a reasonable option for the patients residing in the service area under Dr. Trob's care. Given the high number of pre-ESRD patients (211), living in the immediate area, access to these services must be convenient for the patient, and require small travel times/costs. The applicants note the nearest facilities are either at high occupancy levels, or not yet operational. The applicants identified no costs with this alternative.

2. <u>Propose a Project of Greater or Lesser Scope</u>

The applicants note the only option of lesser scope and cost would be to do nothing, which is not feasible. Given Dr. Trob's growing pre-ESRD population, future access to dialysis services must be acted upon in the present, as opposed to years in the future, when facilities may be over extended. The applicants identified no costs with doing nothing.

3. Pursue a Joint Venture with Another Provider

The applicants rejected this alternative, based on their business model which is to be wholly owned. The applicants have entered in to joint ventures in the past, but feel this option would be imprudent in this situation. The applicants report having a healthy financial position and abundant liquidity, allowing them to support the development/addition of ESRD stations without partnerships or outside financial assistance. The applicants identified a cost identical to the proposed project of \$3,025,690 for this alternative.

4. **Project as Proposed**

The applicants chose this alternative, considering the alternative to establish a new facility would keep the patient's well being at the forefront while planning for future growth in the provision of ESRD services in the Grayslake/Libertyville area. Cost of the proposed alternative: \$3,025,690.

VI. <u>Section 1110.234 - Project Scope and Size, Utilization and Unfinished/Shell Space - Review Criteria</u>

A) Size of Project

The Criterion states:

"The applicant shall document that the amount of physical space proposed for the project is necessary and not excessive. The proposed gross square footage (GSF) cannot exceed the GSF standards of Appendix B, unless the additional GSF can be justified by documenting one of the following:

- 1) Additional space is needed due to the scope of services provided, justified by clinical or operational needs, as supported by published data or studies;
- 2) The existing facility's physical configuration has constraints or impediments and requires an architectural design that results in a size exceeding the standards of Appendix B;
- 3) The project involves the conversion of existing bed space that results in excess square footage."

The applicants propose to establish a 12 station ESRD facility in 7,275 GSF of leased space. The State board standard is 360-520 GSF per station. The applicants note the project is allocating 606 GSF per station, which exceeds the standard by 86 DGSF. The applicants explain that the need for excessive space is for the provision of office space and home training. Regardless, the proposed project exceeds the spatial standards established by the State Board, and a positive finding cannot be made.

TABLE FIVE					
		SIZE OF PROJE			
	1	1-099 FMC Prairie M	leadows		
Department	Department Proposed State Standard Difference Met				
/Service BGSF/DGSF Standard?					
ESRD	7,275 GSF	360-520 DGSF	86 DGSF Over per	No	
Facility	(12 Stations)	(606 GSF/Station)	station		

THE STATE BOARD STAFF FINDS THE PROPOSED PROJECT <u>DOES</u> <u>NOT</u> APPEAR TO BE IN CONFORMANCE WITH THE SIZE OF PROJECT CRITERION (77 IAC 1110.234(a)).

B) Criterion 1110.234 (b) - Project Services Utilization

The applicant shall document that, by the end of the second year of operation, the annual utilization of the clinical service areas or equipment shall meet or exceed the utilization standards specified in Appendix B. The number of years projected shall not exceed the number of historical years documented. If the applicant does not meet the utilization standards in Appendix B, or if service areas do not have utilization standards in 77 Ill. Adm. Code 1100, the applicant shall justify its own utilization standard by providing published data or studies, as applicable and available from a recognized source, that minimally include the following:

The applicants note Dr. Joshua Trob, M.D. identified 211 pre-ESRD patients who reside in close proximity to the Grayslake/Libertyville area, and that 119 of these patients are expected to be referred to the proposed facility, once completed. The applicants have documented by the second year after project completion (2015), they will be above the State Board's target occupancy of 80% (Application, P. 86).

THE STATE BOARD STAFF FINDS THE PROPOSED PROJECT APPEARS TO BE IN CONFORMANCE WITH THE PROJECTED SERVICES UTILIZATION CRITERION (77 IAC 1110.234(b)).

IX. Section 1110.1430 - In-Center Hemodialysis Projects - Review Criteria

The criterion for establishing an ESRD facility reads as follows:

- 1) 77 Ill. Adm. Code 1100 (formula calculation)
 - A) The number of stations to be established for in-center hemodialysis is in conformance with the projected station deficit specified in 77 Ill. Adm. Code 1100, as reflected in the latest updates to the Inventory.
 - B) The number of stations proposed shall not exceed the number of the projected deficit, to meet the health care needs of the population served, in compliance with the utilization standard specified in 77 Ill. Adm. Code 1100.
- 2) Service to Planning Area Residents

- A) Applicants proposing to establish or add stations shall document that the primary purpose of the project will be to provide necessary health care to the residents of the area in which the proposed project will be physically located (i.e., the planning or geographical service area, as applicable), for each category of service included in the project.
- B) Applicants proposing to add stations to an existing incenter hemodialysis service shall provide patient origin information for all admissions for the last 12-month period, verifying that at least 50% of admissions were residents of the area. For all other projects, applicants shall document that at least 50% of the projected patient volume will be from residents of the area.
- C) Applicants proposing to expand an existing in-center hemodialysis service shall submit patient origin information by zip code, based upon the patient's legal residence (other than a health care facility).
- 3) Service Demand Establishment of In-Center Hemodialysis Service

The number of stations proposed to establish a new incenter hemodialysis service is necessary to accommodate the service demand experienced annually by the existing applicant facility over the latest two-year period, as evidenced by historical and projected referrals, or, if the applicant proposes to establish a new facility, the applicant shall submit projected referrals The applicant shall document subsection (b) (3) (A) and either subsection (b) (3) (B) or (C).

A) Historical Referrals

i) If the applicant is an existing facility, the applicant shall document the number of referrals to other facilities, for each proposed category of service, for each of the latest two years.

- ii) Documentation of the referrals shall include: patient origin by zip code; name and specialty of referring physician; name and location of the recipient facility.
- B) Projected Referrals

 The applicant shall provide physician referral letters that attest to:
 - i) The physician's total number of patients (by facility and zip code of residence) who have received care at existing facilities located in the area, as reported to The Renal Network at the end of the year for the most recent three years and the end of the most recent quarter;
 - ii) The number of new patients (by facility and zip code of residence) located in the area, as reported to The Renal Network, that the physician referred for in-center hemodialysis for the most recent year;
 - iii) An estimated number of patients (transfers from existing facilities and pre-ESRD, as well as respective zip codes of residence) that the physician will refer annually to the applicant's facility within a 24-month period after project completion, based upon the physician's practice experience. The anticipated number of referrals cannot exceed the physician's documented historical caseload;
 - iv) An estimated number of existing patients who are not expected to continue requiring in-center hemodialysis services due to a change in health status (e.g., the patients received kidney transplants or expired);
 - v) The physician's notarized signature, the typed or printed name of the physician, the physician's office address and the physician's specialty;

- VI) Verification by the physician that the patient referrals have not been used to support another pending or approved CON application for the subject services; and
- VI i) Each referral letter shall contain a statement attesting that the information submitted is true and correct, to the best of the physician's belief.
- 5) Service Accessibility

The number of stations being established or added for the subject category of service is necessary to improve access for planning area residents. The applicant shall document the following:

- A) Service Restrictions

 The applicant shall document that at least one of the following factors exists in the planning area:
 - i) The absence of the proposed service within the planning area;
 - ii) Access limitations due to payor status of patients, including, but not limited to, individuals with health care coverage through Medicare, Medicaid, managed care or charity care;
 - iii) Restrictive admission policies of existing providers;
 - iv) The area population and existing care system exhibit indicators of medical care problems, such as an average family income level below the State average poverty level, high infant mortality, or designation by the Secretary of Health and Human Services as a Health Professional Shortage Area, a Medically Underserved Area, or a Medically Underserved Population;

v) For purposes of this subsection (b) (5) only, all services within the 30-minute normal travel time meet or exceed the utilization standard specified in 77 Ill. Adm. Code 1100.

b) <u>Planning Area Need Review Criterion</u>

The applicant shall document that the number of stations to be established or added is necessary to serve the planning area's population, based on the following:

1) 77 Ill. Adm. Code 1100 (formula calculation)

According to the March 2012 update to the IDPH Inventory of Health Care Facilities ("Inventory"), shows an excess of 16 stations in the HSA VIII ESRD planning area. This project is requesting to establish a 12-station ESRD facility in 7,275 GSF of leased space in Libertyville. HSA-VIII is comprised of Lake, McHenry, and Kane counties.

2) Service to Planning Area Residents

The primary purpose of this project is to provide in-center ESRD services to the residents of Grayslake/Libertyville and HSA-VIII. The applicants note 100% of the 119 pre-ESRD patients reside in Lake County (Application, p. 88).

3) Service Restrictions

The applicants identified a service area encompassing the counties of Lake, McHenry, and Kane. The applicants note the current excess of 4 ESRD stations in the HSA, and the growing ESRD population under the care of Dr. Joshua Trob, M.D., the referring physician.

4) Service Accessibility

The applicants state the proposed facility will be located in Libertyville (HSA-VIII). The applicants note the need that they are planning for is not in the present, but two to three years in the future. The referring physician, Dr. Trob, M.D., has witnessed a significant increase in the pre-

ESRD patient load (211 patients), and predicts 119 of these patients to utilize FMC Prairie Meadows upon project completion. However, Board Staff notes there are 7 (70%), facilities within 30 minutes of the proposed location, operating beneath the 80th percentile. Two of these facilities are newly established, and will be fully operational by the proposed project's completion date.

Conclusion

Libertyville/Grayslake and the HSA-VIII planning area have experienced significant growth in its pre-ESRD population. Dr. Trob, M.D. has identified a sufficient number of pre-ESRD patients who are expected to use the proposed facility after project completion. There is an excess of 16 stations in the planning area and 70% of the ESRD facilities in the service area are underutilized. Based on these findings, a positive finding cannot be made for this criterion.

THE STATE BOARD STAFF FINDS THE PROPOSED PROJECT DOES NOT APPEAR TO BE IN CONFORMANCE WITH THE PLANNING AREA NEED CRITERION (77 IAC 1110.1430(b)).

- c) Unnecessary Duplication / Maldistribution Review Criterion
 - 1) The applicant shall document that the project will not result in an unnecessary duplication. The applicant shall provide the following information:
 - A) A list of all zip code areas that is located, in total or in part, within 30 minutes normal travel time of the project's site;
 - B) The total population of the identified zip code areas (based upon the most recent population numbers available for the State of Illinois population); and
 - C) The names and locations of all existing or approved health care facilities located within 30 minutes normal travel time from the project site that provide the categories of station service that are proposed by the project.

- The applicant shall document that the project will not result in maldistribution of services. Maldistribution exists when the identified area (within the planning area) has an excess supply of facilities, stations and services characterized by such factors as, but not limited to:
 - A) A ratio of stations to population that exceeds one and onehalf times the State average;
 - B) Historical utilization (for the latest 12-month period prior to submission of the application) for existing facilities and services that is below the utilization standard established pursuant to 77 Ill. Adm. Code 1100; or
 - C) Insufficient population to provide the volume or caseload necessary to utilize the services proposed by the project at or above utilization standards.
- 3) The applicant shall document that, within 24 months after project completion, the proposed project:
 - A) Will not lower the utilization of other area providers below the occupancy standards specified in 77 Ill. Adm. Code 1100; and
 - B) Will not lower, to a further extent, the utilization of other area hospitals that are currently (during the latest 12-month period) operating below the occupancy standards.

There are 10 existing facilities within 30 minutes. 7 (70%) of the facilities are operating below the target occupancy of 80%. Average utilization of the 10 facilities is 55.1%. Given the low average utilization of the facilities within a 30 minute radius, it appears that a duplication of service will result with the establishment of this facility.

The ratio of stations to population within 30 minutes is 1 station per 6,332 per resident. The ratio of stations to population within the State of Illinois is 1 station per 3,508 residents, based on 2010 census figures. While these data illustrate a need for additional stations, 7 of the 10 ESRD facilities in the service area are operating beneath the 80th percentile, and there is an

excess of stations in the planning area. Therefore, a positive finding cannot be made.

THE STATE BOARD STAFF FINDS THE PROPOSED PROJECT DOES NOT APPEAR TO BE IN CONFORMANCE WITH THE UNNECESSARY DUPLICATION/MALDISTRIBUTION CRITERION (77 IAC 1110.1430 (c) (1) (2)).

C) Staffing - Availability

The Criterion states:

"The applicant shall document that relevant clinical and professional staffing needs for the proposed project were considered and that licensure and JCAHO staffing requirements can be met. In addition, the applicant shall document that necessary staffing is available by providing letters of interest from prospective staff members, completed applications for employment, or a narrative explanation of how the proposed staffing will be achieved.

- 1) Qualifications
 - A) Medical Director Medical direction of the facility shall be vested in a physician who has completed a boardapproved training program in nephrology and has at least 12 months experience providing care to patients receiving dialysis.
 - B) Registered Nurse The nurse responsible for nursing services in the unit shall be a registered nurse (RN) who meets the practice requirements of the State of Illinois and has at least 12 months experience in providing nursing care to patients on maintenance dialysis.
 - C) Dialysis Technician This individual shall meet all applicable State of Illinois requirements (see 210 ILCS 62, the End Stage Renal Disease Facility Act). In addition, the applicant shall document its requirements for training and continuing education.
 - D) Dietitian This individual shall be a registered dietitian with the Commission on Dietetic Registration, meet the practice requirements of the State of Illinois (see the Dietetic and Nutrition Services Practice Act [225 ILCS 30]) and have a minimum of one year of professional work

experience in clinical nutrition as a registered dietitian.

E) Social Worker - The individual responsible for social services shall have a Master's of Social Work and meet the State of Illinois requirements (see 225 ILCS 20, the Clinical Social Work and Social Work Practice Act)."

The applicants are proposing to establish a 12-station ESRD facility and have provided the necessary information as required by this criterion on pages 103-108 of the application for permit.

THE STATE BOARD STAFF FINDS THE PROPOSED PROJECT APPEARS TO BE IN CONFORMANCE WITH THE STAFFING CRITERION (77 IAC 1110.1430 (e) (1)).

D) Support Services

The Criteria states:

"An applicant proposing to establish an in-center hemodialysis category of service must submit a certification from an authorized representative that attests to each of the following:

- 1) Participation in a dialysis data system;
- 2) Availability of support services consisting of clinical laboratory service, blood bank, nutrition, rehabilitation, psychiatric and social services; and
- 3) Provision of training for self-care dialysis, self-care instruction, home and home-assisted dialysis, and home training provided at the proposed facility or the existence of a signed, written agreement for provision of these services with another facility."

The applicants are proposing to establish a 12-station ESRD facility and have provided the necessary documentation as required by this criterion on page 109 of the application for permit. The applicants note Advocate Condell Medical Center, Libertyville, will provide Blood bank, Rehabilitation, and Psychiatric services.

THE STATE BOARD STAFF FINDS THE PROPOSED PROJECT IS IN CONFORMANCE WITH THE SUPPORT SERVICES CRITERION (77 IAC 1110.1430 (f)).

- g) Minimum Number of Stations
 The minimum number of in-center hemodialysis stations for an End
 Stage Renal Disease (ESRD) facility is:
 - 1) Four dialysis stations for facilities outside an MSA;
 - 2) Eight dialysis stations for a facility within an MSA.

The proposed 12 station ESRD facility will be located in an MSA. The applicants have met the requirements of this criterion

THE STATE BOARD STAFF FINDS THE PROPOSED PROJECT APPEARS TO BE IN CONFORMANCE WITH THE MINIMUM NUMBER OF STATIONS CRITERION (77 IAC 1110.1430 (g)).

h) Continuity of Care

An applicant proposing to establish an in-center hemodialysis category of service shall document that a signed, written affiliation agreement or arrangement is in effect for the provision of inpatient care and other hospital services. Documentation shall consist of copies of all such agreements.

The applicants have provided the required affiliation agreement on pages 111-114 of the application for permit. The transfer agreement is with Advocate Condell Medical Center, Libertyville. The applicants have met the requirements of this criterion.

THE STATE BOARD STAFF FINDS THE PROPOSED PROJECT APPEARS TO BE IN CONFORMANCE WITH THE CONTINUITY OF CARE CRITERION (77 IAC 1110.1430 (h)).

j) Assurances

The Criterion states:

"The applicant representative who signs the CON application shall submit a signed and dated statement attesting to the applicant understands that:

1) By the second year of operation after the project completion, the

applicant will achieve and maintain the utilization standards specified in 77 Ill. Adm. Code 1100 for each category of service involved in the proposal; and

2) An applicant proposing to expand or relocate in-center hemodialysis stations will achieve and maintain compliance with the following adequacy of hemodialysis outcome measures for the latest 12-month period for which data are available: ≥ 85% of hemodialysis patient population achieves area reduction ratio (URR) ≥ 65% and ≥ 85% of hemodialysis patient population achieves Kt/V Daugirdas .1.2."

The applicants provided the required certification information on page 115 of the application for permit as required of the criterion. The applicants note Fresenius Medical Care patients in Illinois have achieved the following adequacy outcomes, and the same is expected for Fresenius Medical Care Prairie Meadows.

- 92% of patients had a URR \geq 65%
- 95% of patients had a Kt/V \geq 1.2

THE STATE BOARD STAFF FINDS THE PROPOSED PROJECT APPEARS TO BE IN CONFORMANCE WITH THE ASSURANCES CRITERION (77 IAC 1110.1430 (j)).

X. <u>1120.120 - Availability of Funds</u>

The applicant shall document that financial resources shall be available and be equal to or exceed the estimated total project cost plus any related project costs by providing evidence of sufficient financial resources.

The applicants are funding the project with cash and securities totaling \$1,444,727 the FMV of the leases totaling \$1,580,963. A review of the applicants' financial statements indicates that sufficient cash is available to fund the project.

THE STATE BOARD STAFF FINDS THE PROPOSED PROJECT APPEARS TO BE IN CONFORMANCE WITH THE AVAILABILITY OF FUNDS CRITERION (77 IAC 1120.120 (a)).

XI. 1120.130 - Financial Feasibility

A. Criterion 1120.130 - Financial Viability

Financial Viability Waiver
The applicant is NOT required to submit financial viability ratios if:

- 1) All project capital expenditures, including capital expended through a lease, are completely funded through internal resources (cash, securities or received pledges); or
 - HFSRB NOTE: Documentation of internal resources availability shall be available as of the date the application is deemed complete.
- 2) the applicant's current debt financing or projected debt financing is insured or anticipated to be insured by Municipal Bond Insurance Association Inc. (MBIA), or its equivalent; or
 - HFSRB NOTE: MBIA Inc is a holding company whose subsidiaries provide financial guarantee insurance for municipal bonds and structured financial projects. MBIA coverage is used to promote credit enhancement as MBIA would pay the debt (both principal and interest) in case of the bond issuer's default.
- 3) The applicant provides a third-party surety bond or performance bond letter of credit from an A rated guarantor (insurance company, bank or investing firm) guaranteeing project completion within the approved financial and project criteria.

The applicants have qualified for the financial waiver because the project is being funded with internal sources including capital expended through a lease. The applicants are funding the project with cash and securities of \$1,444,727, and the FMV of the lease of \$1,580,963. A review of the applicants' audited financial statements indicates that sufficient cash is available to fund the project.

Table Six outlines Fresenius Medical Care credit rating from all three credit rating agencies. These credit ratings are **opinions** of the three

rating agencies on the ability of a corporation to meet its financial obligation on time and in full. See page 129 of the application for permit for a discussion of these ratings.

TABLE SIX Fresenius Credit Rating					
Standard & Moody's Fitch Poor's					
Corporate Credit Rating	BB	Ba1	BB+		
Outlook	positive	stable	stable		
Secured Debt	BBB-	Baa3	BBB		
Unsecured Debt	BB	Ba2	BB+		

BB—Less vulnerable in the near-term but faces major ongoing uncertainties to adverse business, financial and economic conditions.

Ba1-Speculative investment. Occurs often in deteriorated circumstances, usually problematic to predict future development

'BB'- ratings indicate an elevated vulnerability to default risk, particularly in the event of adverse changes in business or economic conditions over time; however, business or financial flexibility exists which supports the servicing of financial commitments

THE STATE BOARD STAFF FINDS THE PROPOSED PROJECT APPEARS TO BE IN CONFORMANCE WITH THE FINANCIAL FEASIBILITY CRITERION (77 IAC 1120.130 (a)).

XII. <u>Section 1120.140 - Economic Feasibility</u>

A. Criterion 1120.140(a) - Reasonableness of Financing Arrangements

The applicant shall document the reasonableness of financing arrangements by submitting a notarized statement signed by an authorized representative that attests to one of the following:

- 1) That the total estimated project costs and related costs will be funded in total with cash and equivalents, including investment securities, unrestricted funds, received pledge receipts and funded depreciation; or
- 2) That the total estimated project costs and related costs will be funded in total or in part by borrowing because:

- A) A portion or all of the cash and equivalents must be retained in the balance sheet asset accounts in order to maintain a current ratio of at least 2.0 times for hospitals and 1.5 times for all other facilities; or
- B) Borrowing is less costly than the liquidation of existing investments, and the existing investments being retained may be converted to cash or used to retire debt within a 60-day period.

The applicants are funding the project with cash and securities of \$1,444,727, and the FMV of the lease of \$1,580,963. The applicants have provided documentation of internal funding sources for the proposed project, and this criterion is inapplicable.

THE STATE BOARD STAFF FINDS THE REASONABLENESS OF FINANCING ARRANGEMENTS CRITERION IS INAPPLICABLE TO THE PROPOSED PROJECT (77 IAC 1120.140(a)).

B. Criterion 1120.140(b) - Terms of Debt Financing

This criterion is applicable only to projects that involve debt financing. The applicant shall document that the conditions of debt financing are reasonable by submitting a notarized statement signed by an authorized representative that attests to the following, as applicable:

- 1) That the selected form of debt financing for the project will be at the lowest net cost available;
- 2) That the selected form of debt financing will not be at the lowest net cost available, but is more advantageous due to such terms as prepayment privileges, no required mortgage, access to additional indebtedness, term (years), financing costs and other factors;
- 3) That the project involves (in total or in part) the leasing of equipment or facilities and that the expenses incurred with leasing a facility or equipment is less costly than constructing a new facility or purchasing new equipment.

The applicants are funding the project with cash and securities of \$1,444,727, the FMV of the lease of \$1,580,963. The applicants have provided documentation of internal funding sources for the proposed

project, and this criterion is inapplicable

THE STATE BOARD STAFF FINDS THE TERMS OF DEBT FINANCING CRITERION IS INAPPLICABLE TO THE PROPOSED PROJECT (77 IAC 1120.140(b)).

C. Criterion 1120.140(c) - Reasonableness of Project Cost

The applicant shall document that the estimated project costs are reasonable and shall document compliance with the State Board's standards as detailed in 77 IAC 1120.

<u>Modernization Contracts and Contingencies</u> – These costs total \$1,044,327 or \$143.55 per gross square feet. (\$1,044,327/7,275 GSF = \$143.55/GSF) This appears reasonable when compared to the State Board standard of \$176.20/GSF.

<u>Contingencies</u> – These costs total \$94,939. These costs are 10% of modernization costs. This appears reasonable when compared to the State Board standard of 10%-15% of modernization costs.

<u>Architect and Engineering Fees</u> – These costs total \$104,400 or 9.9% of modernization and contingency costs. This appears reasonable when compared to the State Board standard of 9.75% - 14.63% of modernization and contingency costs.

<u>Moveable Equipment</u> - These costs total \$296,000 or \$24,666 per station. This appears reasonable when compared to the State Board standard of \$39,945.

Fair Market Value of Leased Space and Equipment - These costs are \$1,580,963. The State Board does not have a standard for these costs.

THE STATE BOARD STAFF FINDS THE PROPOSED PROJECT APPEARS TO BE IN CONFORMANCE WITH THE REASONABLENESS OF PROJECT COST CRITERION (77 IAC 1120.140 (c)).

D) Criterion 1120.140 (d) - Projected Operating Costs

The applicant shall provide the projected direct annual operating costs (in current dollars per equivalent patient day or unit of service) for the first full fiscal year at target utilization but no more than two years following project completion. Direct cost means the fully allocated costs of salaries, benefits and supplies for the service.

The applicants anticipate the direct operating costs per treatment to be \$92.00. The State Board does not have a standard for these costs.

THE STATE BOARD STAFF FINDS THE PROPOSED PROJECT APPEARS TO BE IN CONFORMANCE WITH THE PROJECT DIRECT OPERATING COSTS CRITERION (77 IAC 1120.140 (d)).

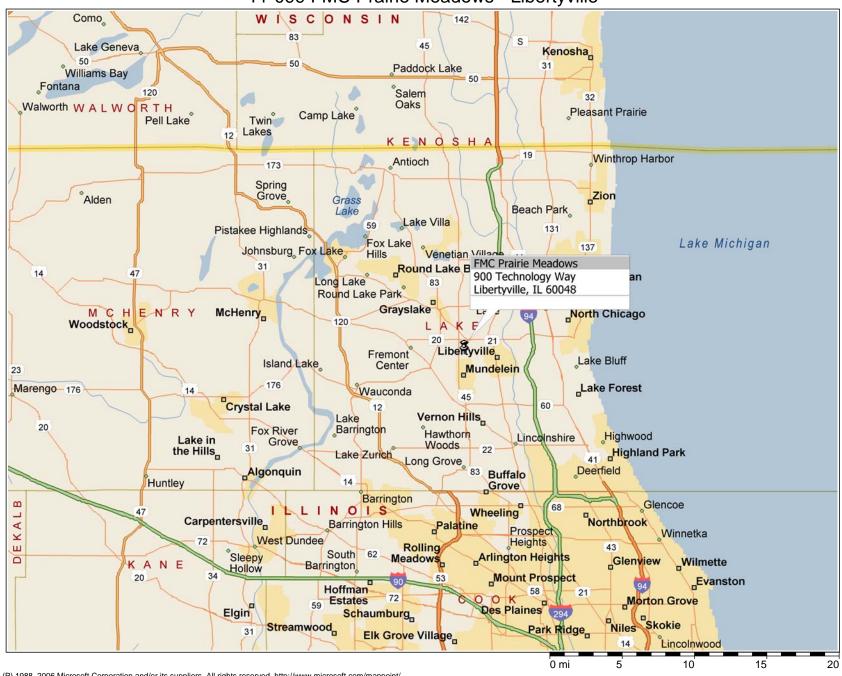
E) Criterion 1120.140 (e) - Total Effect of the Project on Capital Costs

The applicant shall provide the total projected annual capital costs (in current dollars per equivalent patient day) for the first full fiscal year at target utilization but no more than two years following project completion.

The applicants anticipate the total effect of the Project on Capital Costs per treatment to be \$8.73. The State Board does not have a standard for these costs.

THE STATE BOARD STAFF FINDS THE PROPOSED PROJECT APPEARS TO BE IN CONFORMANCE WITH THE TOTAL EFFECT OF THE PROJECT ON CAPITAL COSTS CRITERION (77 IAC 1120.140 (e)).

11-099 FMC Prairie Meadows - Libertyville



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